IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and UCB PHARMA GMBH, Plaintiffs, v. ALKEM LABORATORIES LTD., *et al.*, Defendants.	)	C.A. No. 13-1110-GMS **CONSOLIDATED**

ORDER

WHEREAS, on July 13 through July 16, 2015, the court held a bench trial in the above-captioned consolidated case. The plaintiffs Pfizer Inc. and UCB Pharma GmbH (collectively, "the Plaintiffs") contend that the defendants infringe the asserted claims of the patents-in-suit;

WHEREAS, each of the defendants with the exception of Sandoz, Inc. ("Sandoz") stipulated to infringement of all the asserted claims. Sandoz challenges the Plaintiffs' contention that it infringes claim 1 of U.S. Patent No. 7,384,980 ("the '980 Patent") and claim 3 of U.S. Patent No. 7,855,230 ("the '230 Patent") (collectively, "the disputed claims");

WHEREAS, at the close of the Plaintiffs' production of evidence concerning infringement, both parties moved pursuant to Federal Rule of Civil Procedure 52(c) for judgment on partial findings on the issue of infringement (D.I. 272, 273).

Under Rule 52(c):

> If a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

Fed. R. Civ. P. 52(c). Sandoz makes two procedural arguments concerning the propriety of Dr. Leonard Chyall's expert testimony for the Plaintiffs. (D.I. 272 at 2–3.) First, Sandoz argues that Dr. Chyall offered improper testimony that was beyond the scope of his expert report. Specifically, Sandoz contends that Dr. Chyall did not offer a standard for "one of ordinary skill in the art" in his infringement report, and therefore he could not render an opinion as to the plain and ordinary meaning of the claims. See Fed. R. Civ. P. 26(a)(2). Second, Sandoz asserts that Dr. Chyall's testimony amounts to an untimely claim construction argument.

The court finds Sandoz's procedural arguments unavailing. Such concerns about Dr. Chyall's testimony should have been raised during the final pre-trial conference. Sandoz cannot argue that the scope and content of Dr. Chyall's testimony was unknown to them until trial—his infringement report was specifically identified among the evidentiary issues during the final pre-trial conference. (D.I. 256, Ex. 16, ¶ 3 ("Whether Plaintiffs should be precluded from making untimely claim construction arguments, such as those included in Dr. Chyall's infringement report.").) But when the court presented the defendants—including Sandoz—an opportunity to discuss this very issue during the conference, Sandoz said nothing. (D.I. 262 at 6 ("THE COURT: And Dr. Chyall's infringement reports, who wants to talk about that? No one. Okay.").) Sandoz's failure to argue its positions at the proper time amounts to a waiver of its procedural protestations. Indeed, the court already overruled these very same objections during the course of trial. (Tr. at 105–06, 113–14.) "Trial judges are afforded wide discretion in making rulings on the admissibility of evidence." *Quinn v. Consol. Freightways Corp. of Delaware*, 283 F.3d 572, 576 (3d Cir. 2002). The court sees no reason to reconsider its ruling at this time.

Sandoz finally argues that the substance of Dr. Chyall's testimony was insufficient to establish, by a preponderance of the evidence, the infringement of the disputed claims.

Conversely, the Plaintiffs contend that a judgment of infringement is warranted based on Dr. Chyall's testimony because Sandoz did not present any evidence to the contrary. The court agrees with the Plaintiffs that Dr. Chyall's testimony adequately establishes Sandoz's infringement of the disputed claims.

Dr. Chyall testified that the disputed claims covered fesoterodine generally—*i.e.*, not limited to the free base—and that one of skill in the art would understand that a salt form of fesoterodine was within the scope of the disputed claims. (Tr. at 107, 112, 116.) Next, Dr. Chyall examined Sandoz's Abbreviated New Drug Application ("ANDA") filings and determined that Sandoz's ANDA product included fesoterodine as a hydrogen fumarate salt (Sandoz does not contest this fact). (Tr. at 109–11.) Thus, Dr. Chyall concluded that Sandoz infringes the disputed claims. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996) ("An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." (internal citation omitted)).

The court finds Dr. Chyall's testimony credible and persuasive, especially given the lack of contradictory evidence from Sandoz. The court examines each claim in turn. Claim 1 of the '980 Patent claims: "R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester," or the R-isomer of fesoterodine. '980 Patent, claim 1. Importantly, claim 2 recites "a salt of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester with a physiologically acceptable acid," *i.e.*, the salt form of claim 1. '980 Patent, claim 2.

> [T]here is . . . a presumption that two independent claims have different scope when different words or phrases are used in those claims. However, the [claim differentiation] doctrine only creates a presumption that each claim in a patent has a different scope; it is

> not a hard and fast rule of construction. . . . Claims that are written in different words may ultimately cover substantially the same subject matter.

Seachange Int'l, Inc. v. C-COR, Inc., 413 F.3d 1361, 1368–69 (Fed. Cir. 2005) (internal citations, alterations, and quotation marks omitted). While Sandoz may have had a colorable claim differentiation argument, it never asked the court to construe claim 1 as excluding salt forms of fesoterodine, nor did it present expert testimony that one skilled in the art would read claim 1 as excluding salt forms of fesoterodine. "When the parties raise an actual dispute regarding the proper scope of the[] claims, the court . . . must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). Here, the court was not presented with an *actual* dispute—the only opinion is that of Dr. Chyall, who testified that one of skill in the art would read claim 1 as covering salt forms, in addition to the free base form. (Tr. at 116 ("[The disputed claims] cover fesoterodine without any limitations of form. So fesoterodine fumarate would be covered by that.").) During cross-examination, Dr. Chyall consistently maintained that claim 1 covered salt forms of fesoterodine, despite the different characteristics of fesoterodine free base and the hydrogen fumarate salt. (Tr. at 116–36.) The court is satisfied that the Plaintiffs have proven by a preponderance of the evidence that Sandoz infringes claim 1 of the '980 Patent.

Claim 1 of the '230 Patent (stipulated) recites a method of treating urinary incontinence using one of several chemical compounds, among them, festoterodine:

> A method of treating urinary incontinence in a patient in need thereof, the method comprising administering to the patient an effective amount of a compound selected from the group consisting of:
>
> > [compound 1], isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester [*i.e.*, fesoterodine], [compound 3], and [compound 4], including the racemic mixtures and individual enantiomers of said compounds, and a salt of said compounds with a physiologically acceptable acid.

'230 Patent, claim 1. Claim 3 (one of the disputed claims) depends from claim 1 and recites:

> The method according to claim 1, wherein the compound is R-(+) isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester.

'230 Patent, claim 3. Thus, claim 3 selects fesoterodine from among the four possible compounds identified in claim 1. Moreover, whereas claim 1 is directed to "the racemic mixtures and individual enantiomers of said compounds," claim 3 specifies the R-isomer of fesoterodine. Claim 3 did nothing, however, to further narrow the final limitation of claim 1: "including . . . a salt of said compounds with a physiologically acceptable acid." *See* 35 U.S.C. § 112(d) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.").

Dr. Chyall testified that claim 3 of the '230 Patent covers a method of treating urinary incontinence using fesoterodine hydrogen fumarate, and therefore Sandoz's ANDA product infringes the claim. (Tr. at 113, 115, 134.) Sandoz did not provide an opposing expert opinion. The court finds Dr. Chyall's testimony highly convincing. Unlike claim 1 for the '980 Patent (discussed previously), claim 3 of the '230 Patent does not face any potential claim differentiation problem. Claim 1 of the '230 Patent specifically covers salt forms of the various named compounds. Claim 3—which depends from claim 1 and therefore incorporates the same limitations—includes salt forms as well.

WHEREAS, the court having considered the evidence presented at trial, the parties' submitted papers, and the applicable law;

IT IS HEREBY ORDERED THAT:

1. The Plaintiff's Motion for Judgment under Rule 52(c) (D.I. 273) is GRANTED;

2. Sandoz's Motion for Judgment under Rule 52(c) (D.I. 272) is DENIED;

3. To the extent the claims are valid, Sandoz INFRINGES (a) claim 1 of U.S. Patent No. 7,384,980 and (b) claim 3 of U.S. Patent No. 7,855,230.

Dated: July 21, 2015

UNITED STATES DISTRICT JUDGE